a certify that this paper is being deposited with the USPS, addressed to the tent and Trademark Office, with sufficient first class postage on May 7, 2004.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Docket No.:

SHLI-035-002

CHANG et al.

Etisa Lane

Group Art Unit:

Not yet assigned

Application No.: 10/770,727

Examiner:

Not yet assigned

Filed: February 2, 2004

Title:

DRUG FORMULATION AND DELIVERY USING CRYSTALLINE

METHYLATED CYCLODEXTRINS

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

May 7, 2004

Sir:

Submitted herewith is PTO/SB/08A, listing references to be considered during the examination of this application. The Examiner is requested to consider the reference, and list them on the front page of any patent issuing herefrom.

This paper is considered to be timely, because it is being filed either before the issuance of a first Office Action and/or before the expiration of three months from the filing date. Therefore, no fee is due with this paper.

Respectfully submitted,

SHIRE LABORATORIES INC. 1550 East Gude Drive Rockville, MD 20850

Tel: 301/838-2658 Fax: 301/838-2501

Email: elane@shirelabs.com

M. Elisa Lane

Redistration No. 34,409 Attorney for Applicants

PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031 U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

Complete if Known			
Application Number	10/770,727		
Filing Date	February 2, 2004		
First Named Inventor	CHANG		
Art Unit	not yet assigned		
Examiner Name	not yet assigned		
Attorney Docket Number	SHLI-035-002		

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2 (d known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,681,828	-	Pitha	
		US- 5 935 941		Pitha	
		<sup>US-</sup> 6,110,498		Rudnic et al.	
		<sup>US-</sup> 6,284,276		Rudnic et al.	
		US-			
		US-	"		
		US-			

FOREIGN PATENT DOCUMENTS						
Examiner Cite	Cite No.1		Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	MM-DD-YYYY		Or Relevant Figures Appear	T
						L
						Ĺ
						L
	i		i			[

Examiner	Date	
Signature	Considered	
	l l	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.